



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 660, 801, and 809

[Docket No. FDA-2013-N-0125]

RIN 0910-AG74

Use of Certain Symbols in Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise medical device and biological product labeling regulations to explicitly allow for the inclusion of stand-alone graphical representations of information, or symbols, if the symbol has been established as part of a standard developed by a nationally or internationally recognized standards development organization (SDO) (referred to in this document as a “standardized symbol”) and such standardized symbol is part of a standard recognized by FDA for use on the labeling of medical devices (or on a subset of medical devices), provided that such symbol is explained in a symbols glossary that contemporaneously accompanies the medical device. FDA is also proposing to revise prescription device labeling regulations to authorize the use of the symbol statement “Rx only” on the labeling of prescription devices.

DATES: Submit electronic or written comments on the proposed rule by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL

REGISTER], (see section VII). See section IX for the proposed effective date of a final rule based on the proposed rule in this document.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2013-N-0125 and/or Regulatory Information Number (RIN) 0910-AG74, by any of the following methods, except that comments on information collection issues under the PRA must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see section VII).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following way:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, Docket No. FDA-2013-N-0125, and RIN 0910-AG74 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see section VIII.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading

of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Michael Ryan,
Center for Devices and Radiological Health,
Food and Drug Administration,
10903 New Hampshire Ave.,
Bldg. 66, rm. 1615,
Silver Spring, MD 20993,
301-796-6283; or
Stephen Ripley,
Center for Biologics Evaluation and Research (HFM-17),
Food and Drug Administration,
1401 Rockville Pike, suite 200N,
Rockville, MD 20852,
301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

Medical device labeling¹ is intended to clearly communicate information to end users, including manufacturer identification, intended use, and directions for use. Section 502 of the

¹Under section 201(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(m)), the term “labeling” means all labels and other written, printed, or graphic matter: (1) Upon any article or any of its containers or wrappers or (2) accompanying such article. Under section 201(k) of the FD&C Act, the term “label” means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of the FD&C Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside

FD&C Act (21 U.S.C. 352) requires that industry provide clear and understandable labeling for FDA-regulated products. A device is deemed misbranded, among other reasons, if its labeling is false or misleading (section 502(a)), if the required information on the labeling fails to appear in terms that are “likely to be read and understood by the ordinary individual under customary conditions of purchase and use” (section 502(c)), or if its labeling does not bear “adequate directions for use” (section 502(f) of the FD&C Act).

FDA has further defined labeling requirements for devices by regulation, requiring, in part 801 (21 CFR part 801), that “[a]ll words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language...” (§ 801.15(c)(1)). The regulation goes on to allow for use of foreign language under certain circumstances, but does not mention the use of graphics, pictures, or symbols to communicate information. Under the current regulation, graphics, pictures, or symbols in labeling that represent required information must be accompanied by explanatory English text adjacent to the symbol in order to “appear thereon in the English language.”

Under § 801.119, labeling for in vitro diagnostic (IVD) devices has adequate directions for use if it meets the requirements of § 809.10 (21 CFR 809.10), which prescribes the statements, declarations, and other information that IVD devices must display on their labeling. Although § 809.10 does not explicitly authorize the use of symbols, the Agency has interpreted this regulation generally to allow graphics, pictures, or symbols to meet the labeling requirements of this regulation except where this regulation specifies particular labeling language.

The FD&C Act also applies to biological products defined in section 351(i)(1) of the Public Health Service Act (PHS Act) (42 U.S.C 262(i)).² See, specifically, PHS Act section 351(j) (42 U.S.C. 262(j)). Accordingly, biological products that are also medical devices are subject to the labeling requirements of section 502 of the FD&C Act (applicable to any “word, statement or other information required by or under authority of [the FD&C] Act to appear on the label or labeling” of a medical device), as well as the regulations of part 801, including § 801.15. The part 660 (21 CFR part 660) labeling regulations applicable to certain biologic diagnostic substances for laboratory tests refer to the labeling requirements of § 809.10. See §§ 660.2 (for Antibody to Hepatitis B surface Antigen), 660.28 (for Blood Grouping Reagent), 660.35 (for Reagent Red Blood Cells), § 660.45 (for Hepatitis B Surface Antigen), and 660.55 (for Anti-Human Globulin).

The Food and Drug Administration Modernization Act (FDAMA) added section 514(c) to the FD&C Act (21 U.S.C. 360d(c)). This provision authorizes FDA to “recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization,” for which a person may then submit a declaration of conformity in order to meet a premarket submission or other requirement under the FD&C Act when the standard applies to and satisfies the requirement, including a labeling requirement. Section 514(c)(2) of the FD&C Act also authorizes FDA to withdraw recognition of a standard through publication of a notice in the Federal Register if FDA determines that the standard is no longer appropriate for meeting a device requirement under the FD&C Act. Congress noted with approval the past work of SDOs, such as the American National Standards Institute (ANSI), the

² “The term ‘biological product’ means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.” (42 U.S.C 262(i))

International Organization for Standardization (ISO), and the International Electrotechnical Commission in the field of medical device products from “[l]ong before the enactment of the Medical Device Amendments of 1976” (S. Rep. No. 43, 105th Cong., 1st Sess. 23 (1997)).

Section 514(c) of the FD&C Act requires FDA to publish in the Federal Register the names of all standards to which recognition has been given. See the Center for Devices and Radiological Health’s (CDRH’s) public database at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm> for the most recent FDA listing of recognized consensus standards. In “Guidance for Industry and FDA Staff: CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition,” FDA set forth its procedures for recognition of consensus standards. This guidance is available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077322.pdf>. Further information about the recognition of consensus standards can be found in FDA’s “Guidance for Industry and FDA Staff: Frequently Asked Questions on Recognition of Consensus Standards,” available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm075064.pdf>. FDA published the initial list of recognized consensus standards in the Federal Register of February 25, 1998 (63 FR 9561).

Modifications to the initial and previous lists of recognized standards--announcing the addition, withdrawal, and revision of such standards--are published in the Federal Register. Changes in a recognized standard, including changes to a standardized symbol recognized in such standard, do not retroactively affect a product’s clearance or approval status. The most recent modifications to the list of recognized standards, including a complete list of the 29

previous modifications, was published in the Federal Register on January 15, 2013 (78 FR 2998).

In addition, the Agency maintains hypertext markup language and portable document format (PDF) versions of the list of “FDA Recognized Consensus Standards.” Both versions are publicly accessible at the Agency’s Internet site at

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. Interested persons should review the supplementary information sheet (SIS) published for the standard to understand fully the extent to which FDA recognizes the standard.

While section 503(b)(4) of the FD&C Act (21 U.S.C. 353(b)(4)) allows the labels of prescription drug products to contain the symbol statement “Rx only,” this provision is not applicable to prescription devices. In order to give manufacturers, repackers, relabelers, and distributors more labeling options for prescription devices, CDRH issued the guidance, “Alternative to Certain Prescription Device Labeling Requirements” on January 21, 2000, which is available at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085404.htm>. It announced CDRH’s intent to exercise enforcement discretion with respect to the use of the symbol statement “Rx only” on prescription medical device labeling as an alternative to the prescription use statement in § 801.109.

II. Proposed Revision to Parts 660, 801, and 809

FDA is proposing to revise parts 660, 801, and 809 to expressly allow for the use in medical device labeling of certain “stand-alone” symbols (not accompanied by explanatory text adjacent to the symbol) contained in a standard that FDA recognizes under its authority under section 514(c) of the FD&C Act, as long as a “symbols glossary” contemporaneously accompanies the device. The term “symbols glossary” means a compiled listing of each symbol

used in the labeling of the device and of the meaning of or explanatory text for the symbol. As discussed previously, the current regulations do not mention the use of symbols. The medical device industry has requested permission to use stand-alone symbols in device labeling in order to make the label more user-friendly by replacing small, difficult-to-read text with pictorial information and to harmonize the labeling requirements of U.S. and foreign regulatory bodies.

Various symbols with accompanying text have been used in health product labeling for several years, both on package labels and within other labeling documents, such as the instructions for use. The proposed rule will continue to allow the use of symbols, including standardized symbols, on device labeling when the symbols are accompanied by explanatory adjacent text. For IVD devices intended for health professional use, CDRH and the Center for Biologics Evaluation and Research have interpreted applicable labeling requirements to allow the use of certain symbols contained in a standard recognized by FDA in labeling without explanatory text adjacent to the symbol. See FDA guidance entitled “Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use,” issued November 30, 2004. Additionally, CDRH has exercised enforcement discretion with respect to the prescription use symbol statement “Rx Only” (without accompanying explanatory text). See FDA guidance entitled “Alternative to Certain Prescription Device Labeling Requirements,” issued January 21, 2000, available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072747.htm>.

In the international community, voluntary standards such as ISO 15223, originally published in 2000, have standardized, commonly-used symbols that are often used in U.S. device

labeling with adjacent explanatory text, and in limited instances, without adjacent text for IVD devices.

In Europe, the widespread use of symbols in medical device labeling is in response to the European Commission's 1993 Medical Device Directive, which states that any text present on a medical device label must be present in all languages so that it can be understood by end users in multiple countries. The Medical Device Directive 93/42/EEC states in Annex I: "Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device." Thus, manufacturers may produce medical device labels that include symbols without accompanying text for the European market. At present, that same label must be revised to either remove the symbol or add accompanying explanatory text, in English, to enter the U.S. market. This regulatory difference has created confusion and generated industry complaints that manufacturers have to develop different labels for each market.

Under our proposed rule revising parts 660, 801, and 809, FDA seeks to harmonize U.S. regulatory requirements with those of the European Commission by allowing stand-alone standardized symbols recognized by FDA to be used in medical device labeling when a symbols glossary contemporaneously accompanies the medical device.

Based on the process of recognizing consensus standards under section 514(c) of the FD&C Act and taking into consideration FDA's allowance of symbols on some medical devices for nearly a decade, FDA believes that certain symbols contained in national or international standards are "likely to be read and understood by the ordinary individual under customary conditions of purchase and use" (section 502(c) of the FD&C Act). Thus, FDA is proposing to

allow for the use of certain stand-alone symbols, contained in standards recognized by FDA, on device labeling (including labels) in the United States, so long as a symbols glossary contemporaneously accompanies the medical device. FDA's Web site will contain up-to-date information on which standardized symbols are recognized by FDA. One example of an international symbols standard is the Association for the Advancement of Medical Instrumentation (AAMI)/ANSI/ISO 15223-1:2012, Medical Devices--Symbols to be Used With Medical Device Labels, Labeling and Information to be Supplied, Part 1, General Requirements. This standard is currently recognized in part by FDA as a standard containing medical device-specific symbols that may be used without accompanying text on labeling for IVD devices intended for use by health professionals.

FDA is issuing this regulation to permit the use of stand-alone symbols in device labeling under certain circumstances. FDA intends to describe its policy for the appropriate use of symbols in device labeling in a separate guidance document and to identify the specific standardized symbols recognized and the scope of devices affected through its standards recognition process. Generally, FDA will consider recognizing symbols included in standards if the Agency determines that the device user, under customary conditions of purchase and use, will understand the meaning of the symbol and the message it was intended to convey. (See section 502(c) of the FD&C Act.). This understanding can be demonstrated by applying a validation process that complies with an appropriate symbol validation standard, such as AAMI/ANSI/ISO 15223-2:2010 (Part 2), Symbol Development, Selection and Validation. Under this process, studies need to demonstrate end-user comprehension of the symbol in context and validation data may be submitted to the SDO for its review.

On its own initiative and in response to requests received from the public, FDA expects to assess standardized symbols from time to time as part of its consensus standards recognition process. FDA will consider recognizing symbols contained in standards developed by SDOs that follow a process where the standard development is transparent (i.e., open to public scrutiny), where the participation is balanced, where an appeals process is included, where the standard is not in conflict with any statute, regulation, or policy under which FDA operates, and where the standard is national or international in scope.

Ordinarily, only standardized symbols that have undergone the SDO's written procedures for approval/issuance and validation will be recognized. FDA does not intend to recognize symbols that have not been validated through SDO procedures nor does FDA intend to recognize proprietary symbols. Under FDA's consensus standards recognition process, the SDO, not FDA, would review validation data supporting the use of each standardized symbol. On the SIS for each standard it recognizes, FDA will include a list of device types or categories affected by the recognition. This standards recognition process will not be changed by the proposed rule.

It is important to note that any stand-alone symbol that conveys information that is required to appear on the labeling of a device would be subject to the requirements under the proposed amendment to § 801.15(c)(1) that the symbol would have to be recognized by FDA, used within any parameters of such recognition, and be explained in a symbols glossary that contemporaneously accompanies the device. Under section 502(f)(1) of the FD&C Act, device labeling is required to provide adequate directions for use to the user of a device. See §§ 801.5 and 801.109. Therefore, any stand-alone symbol on the labeling of a device that conveys directions for use would be subject to the symbols glossary requirements under the proposed amendment to § 801.15(c)(1).

FDA is proposing to revise § 801.109(b)(1), as well as § 801.15(c)(1), to include language that affirmatively permits use of the symbol statement “Rx only,” without accompanying explanatory text, as an alternative to the prescription device label statement “Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner).” It is important to note that the word “only” needs to immediately follow the symbol “Rx.” However, the symbol statement “Rx only” does not necessarily need to be bracketed in quotation marks, and the word “only” may appear in upper or lower case letters, for example, Rx only, Rx Only, or Rx ONLY. As in the case of labels for prescription drugs, the new label statement for prescription medical devices may be printed as either “Rx only” or “**R**x only.” (See 67 FR 4904; February 1, 2002.) The **R** symbol in the symbol statement “Rx only” or the symbol statement “Rx only” in its entirety may be printed in bold or in regular type.

The proposed amendments to §§ 801.15 and 809.10 would also cover biological products regulated as devices. This rule also proposes to amend the specific labeling requirements applicable to biological products in part 660 to allow for the labeling use of standardized symbols that FDA recognizes under its authority under section 514(c) of the FD&C Act, as long as there is a “symbols glossary” in the labeling that contemporaneously accompanies the product. We have also proposed changes in part 660 to describe more uniformly the labeling requirements applicable to licensed products subject to this part: diagnostic substances for laboratory tests.

III. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Legal Authority for the Proposed Rule

Section 514(c)(1)(A) of the FD&C Act authorizes FDA to recognize, by publication in the Federal Register, “all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket submission requirement or other requirement under the FD&C Act to which such standard is applicable.” Section 514(c)(2) of the FD&C Act allows FDA to withdraw recognition of a standard through publication of a notice in the Federal Register if FDA determines that the standard is no longer appropriate for meeting a device requirement under the FD&C Act. In addition, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) authorizes the Agency to issue regulations for the efficient enforcement of the FD&C Act.

A device is misbranded under section 502(a) of the FD&C Act if its labeling is false or misleading in any particular. Additionally, a device is misbranded under section 502(c) of the FD&C Act if “any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.” A device is also misbranded under section 502(f) of the FD&C Act unless its labeling bears adequate directions for use.

Under section 201(m) of the FD&C Act (21 U.S.C. 321(m)), the term “labeling” means all labels and other written, printed, or graphic matter: (1) Upon any article or any of its containers or wrappers or (2) accompanying such article. Under section 201(k) of the FD&C Act, the term “label” means a display of written, printed, or graphic matter upon the immediate

container of any article; and a requirement made by or under authority of [the FD&C Act] that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule imposes no new burdens, the Agency proposes to certify that the final rule would not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold

after adjustment for inflation is \$139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

Summary: The proposed rule would provide medical device manufacturers with the option to use certain stand-alone symbols contained in a standard recognized by FDA to communicate information to end users as an alternative way to use these standardized symbols on device labeling without explanatory adjacent text as long as the device is contemporaneously accompanied by an explanatory symbols glossary.

Medical device manufacturers would only adopt the proposed rule if they expect a positive net benefit (estimated benefits minus estimated costs). Hence, the rule is expected to provide a non-negative net benefit to each adopting manufacturer. Choosing to adopt the rule would potentially reduce the costs associated with designing and re-designing the labels on medical devices that are currently sold in the United States and the European Union. The estimated annual benefits range from \$8.1 million to \$26.1 million at a 3 percent discount rate, and \$7.9 million to \$25.6 million at a 7 percent discount rate. Adopting the rule would incur one-time administrative costs, which we estimate to range from \$2.4 million to \$9.5 million. Annualized over 20 years, the estimated net benefits associated with adopting the proposed rule range from \$7.8 million to \$25.5 million at a 3 percent discount rate, and \$7.6 million to \$24.6 million at a 7 percent discount rate. The costs and benefits accrue to the same entities, however, so any firm making the change to symbols would, on net, reduce costs.

FDA also examined the economic implications of the proposed rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires Agencies to analyze regulatory

options that would lessen the economic effect of the rule on small entities. We approximately estimated the proposed rule's impact on small entities using the percent costs per Universal Products Code (UPC): The ratio between unit labeling costs and revenues among small entities. Our estimates indicate that the average percent costs per UPC ranges from 0 to 48 percent. Because companies can choose to use symbols, the Agency concludes that this rule would not have a significant adverse impact on any small entities. Furthermore, our analysis suggests that companies could reap moderate cost savings via switching to using symbols. On average, companies who switch to using symbols could expect to receive an average annual cost savings ranging from \$1,000 to \$4,000 per UPC. As a result, it is possible that providing medical device manufacturers with the option to use symbols may encourage companies, including small entities, to either start exporting products or export more products

The full discussion of the economic impacts (Ref. 1) is available in docket FDA-2013-N-0125 and at

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). A description of these provisions is given in the Description section of this document with an estimate of the annual third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Medical Devices: Use of Certain Symbols in Labeling--Glossary to Support the Use of Symbols in Labeling.

Description: FDA is proposing to revise medical device and biological product labeling regulations to explicitly allow for the use in medical device labeling of certain stand-alone symbols contained in a standard that FDA recognizes under its authority under section 514(c) of the FD&C Act.

In particular, FDA will allow the inclusion of certain stand-alone graphical representations of information, or symbols, if the symbol has been established as part of a

standard developed by a nationally or internationally recognized SDO and such standardized symbol is part of a standard recognized by FDA for use on the labeling of medical devices, provided that such symbol is explained in a symbols glossary that contemporaneously accompanies the medical device.

As such the requirement to submit to FDA and disclose to third-parties a symbols glossary, which means “a compiled listing of (i) each symbol used in the labeling of the device, and (ii) the meaning of or explanatory text for the symbol,” is subject to the PRA.

Description of Respondents: The likely respondents for this collection of information are domestic and foreign device manufacturers who plan to use stand-alone symbols on the labels and/or labeling of their devices.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden ¹

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Glossary	3,000	1	3,000	1	3,000

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Third Party Disclosure Burden ¹

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Glossary	3,000	1	3,000	4	12,000

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated burden is based on the data in a similar collection for recommended glossary and educational outreach approved under OMB control number 0910-0553 (Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use).

In addition to the proposed third-party disclosure requirements referenced previously, this proposed rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the Paperwork Reduction

Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subpart B have been approved under OMB control number 0910-0231; the collections of information under part 801 and § 809.10 have been approved under OMB control number 0910-0485; and the collections of information in §§ 660.2, 660.28, 660.35, 660.45, and 660.55 have been approved under OMB control number 0910-0338.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the title “Use of Symbols in Labeling.”

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the Federal Register.

VIII. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IX. Proposed Effective Date

FDA is proposing that any final rule based on this proposal become effective 90 days after the date of its publication in the Federal Register or at a later date if stated in the final rule.

X. Reference

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at <http://www.regulations.gov>.

1. Use of Symbols in Medical Device Labeling: Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis.

List of Subjects

21 CFR Part 660

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 809

Labeling, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq., as amended), the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 660, 801, and 809 be amended as follows:

PART 660--ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

1. The authority citation for 21 CFR part 660 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372; 42 U.S.C. 216, 262, 263, 263a, 264.

2. Amend § 660.2 by revising paragraph (c) introductory text to read as follows:

§ 660.2 General requirements.

* * * * *

(c) Labeling. In addition to the applicable labeling requirements of §§ 610.62 through 610.65 and § 809.10 of this chapter, and in lieu of the requirements in §§ 610.60 and 610.61 of this chapter, the following information shall be included. The applicant may provide the labeling information referenced in this subsection in the form of a symbol, provided that such symbol is either accompanied by explanatory text adjacent to the symbol or is contained in a standard that FDA recognizes under its authority under section 514(c) of the Federal Food, Drug, and Cosmetic Act and is explained in a symbols glossary that contemporaneously accompanies the biological product. The term “symbols glossary” means a compiled listing of each symbol used in the labeling of the biological product and of the meaning of or explanatory text for the symbol.

* * * * *

3. Amend § 660.28 by revising the introductory text to read as follows:

§ 660.28 Labeling.

In addition to the applicable labeling requirements of §§ 610.62 through 610.65 and § 809.10 of this chapter, and in lieu of the requirements in §§ 610.60 and 610.61 of this chapter, the following requirements shall be met. The applicant may provide the labeling information referenced in this section in the form of a symbol, provided that such symbol is either accompanied by explanatory text adjacent to the symbol or is contained in a standard that FDA recognizes under its authority under section 514(c) of the Federal Food, Drug, and Cosmetic Act and is explained in a symbols glossary that contemporaneously accompanies the biological

product. The term “symbols glossary” means a compiled listing of each symbol used in the labeling of the biological product and of the meaning of or explanatory text for the symbol.

* * * * *

4. Amend § 660.35 by revising the introductory text to read as follows:

§ 660.35 Labeling.

In addition to the applicable labeling requirements of §§ 610.62 through 610.65 and § 809.10 of this chapter, and in lieu of the requirements in §§ 610.60 and 610.61 of this chapter, the following requirements shall be met. The applicant may provide the labeling information referenced in this section in the form of a symbol, provided that such symbol is either accompanied by explanatory text adjacent to the symbol or is contained in a standard that FDA recognizes under its authority under section 514(c) of the Federal Food, Drug, and Cosmetic Act and is explained in a symbols glossary that contemporaneously accompanies the biological product. The term “symbols glossary” means a compiled listing of each symbol used in the labeling of the biological product and of the meaning of or explanatory text for the symbol.

* * * * *

5. Amend § 660.45 by revising the introductory text to read as follows:

§ 660.45 Labeling.

In addition to the applicable labeling requirements of §§ 610.62 through 610.65 and § 809.10 of this chapter, and in lieu of the requirements in §§ 610.60 and 610.61 of this chapter, the following information shall be included. The applicant may provide the labeling information referenced in this section in the form of a symbol, provided that such symbol is either accompanied by explanatory text adjacent to the symbol or is contained in a standard that FDA recognizes under its authority under section 514(c) of the Federal Food, Drug, and Cosmetic Act

and is explained in a symbols glossary that contemporaneously accompanies the biological product. The term “symbols glossary” means a compiled listing of each symbol used in the labeling of the biological product and of the meaning of or explanatory text for the symbol.

* * * * *

6. Amend § 660.55 by revising the introductory text to read as follows:

§ 660.55 Labeling.

In addition to the applicable labeling requirements of §§ 610.62 through 610.65 and § 809.10 of this chapter, and in lieu of the requirements in §§ 610.60 and 610.61 of this chapter, the following requirements shall be met, The applicant may provide the labeling information referenced in this section in the form of a symbol, provided that such symbol is either accompanied by explanatory text adjacent to the symbol or is contained in a standard that FDA recognizes under its authority under section 514(c) of the Federal Food, Drug, and Cosmetic Act and is explained in a symbols glossary that contemporaneously accompanies the biological product. The term “symbols glossary” means a compiled listing of each symbol used in the labeling of the biological product and of the meaning of or explanatory text for the symbol.

* * * * *

PART 801--LABELING

7. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

8. Amend § 801.15 by revising the section heading and paragraph (c)(1) to read as follows:

§ 801.15 Medical devices; prominence of required label statements; use of symbols in labeling.

* * * * *

(c)(1) All words, statements, and other information required by or under authority of the Federal Food, Drug, and Cosmetic Act to appear on the label or labeling of a device shall appear thereon in one or more of the following formats:

(i) The English language;

(ii) In the case of articles distributed solely in Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English;

(iii) A symbol accompanied by adjacent explanatory English text, or text in the predominant language of the Territory, in the case of articles distributed solely in Puerto Rico or in a Territory where the predominant language is one other than English ;

(iv) A symbol not accompanied by adjacent explanatory text contained in a standard that FDA recognizes under its authority under section 514(c) of the Federal Food, Drug, and Cosmetic Act provided that such symbol is explained in a symbols glossary that contemporaneously accompanies the device. FDA may recognize a standardized symbol for all devices or only for certain types or categories of devices. The term “symbols glossary” means a compiled listing of each symbol used in the labeling of the device and of the meaning of or explanatory text for the symbol;

(v) The symbol statement “Rx only” or “℞ only” may be used as provided under § 801.109(b)(1).

* * * * *

9. Amend § 801.109 by revising paragraph (b)(1) to read as follows:

§ 801.109 Prescription devices.

* * * * *

(b) * * *

(1) The symbol statement “Rx only” or the statement “Caution: Federal law restricts this device to sale by or on the order of a _____”, the blank to be filled with the word “physician”, “dentist”, “veterinarian”, or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

* * * * *

PART 809--IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

10. The authority citation for 21 CFR part 809 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 355, 360b, 360c, 360d, 360h, 360i, 360j, 371, 372, 374, 381.

11. Amend § 809.3 by adding paragraph (c) to read as follows:

§ 809.3 Definitions.

* * * * *

(c) The term “symbols glossary” means a compiled listing of each symbol used in the labeling of the in vitro diagnostic product and of the meaning of or explanatory text for the symbol.

* * * * *

12. Amend § 809.10 by revising the paragraph (a) introductory text, the first sentence in paragraph (b), and paragraphs (c)(2) introductory text, (d) introductory text, (e)(1) introductory text, and (f) introductory text to read as follows:

§ 809.10 Labeling for in vitro diagnostic products.

(a) The label for an in vitro diagnostic product shall state the following information, except where such information is not applicable, or as otherwise specified in a standard for a particular product class, as provided in paragraph (e) of this section, or in the form of a symbol, provided that such symbol is either accompanied by explanatory text adjacent to the symbol or is contained in a standard that FDA recognizes under its authority under section 514(c) of the Federal Food, Drug, and Cosmetic Act and is explained in a symbols glossary that contemporaneously accompanies the in vitro diagnostic product. FDA may recognize a standardized symbol for all devices or only for certain types or categories of devices. Section 201(k) of the Federal Food, Drug, and Cosmetic Act provides that a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless a word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

* * * * *

(b) Labeling accompanying each product, e.g., a package insert, shall state in one place the following information in the format and order specified in this paragraph, except where such information is not applicable, or as specified in a standard for a particular product class, or where such information is provided in the form of a symbol, provided that such symbol is either accompanied by explanatory text adjacent to the symbol or is contained in a standard that FDA recognizes under its authority under section 514(c) of the Federal Food, Drug, and Cosmetic Act and is explained in a symbols glossary that contemporaneously accompanies the in vitro diagnostic product. * * *

* * * * *

(c) * * *

(2) In the case of a shipment or delivery for an investigation that is not subject to part 812 (see § 812.2(c)), if the following conditions are met, including that, where information required by those conditions is provided in the form of a symbol, such symbol must either be accompanied by explanatory text adjacent to the symbol or contained in a standard that FDA recognizes under its authority under section 514(c) of the Federal Food, Drug, and Cosmetic Act, and explained in a symbols glossary that contemporaneously accompanies the in vitro diagnostic product:

* * * * *

(d) The labeling of general purpose laboratory reagents (e.g., hydrochloric acid) and equipment (e.g., test tubes and pipettes) whose uses are generally known by persons trained in their use need not bear the directions for use required by § 809.10(a) and (b), if their labeling meets the requirements of this paragraph, except where such information is provided in the form of a symbol, provided that such symbol is either accompanied by explanatory text adjacent to the symbol or is contained in a standard that FDA recognizes under its authority under section 514(c) of the Federal Food, Drug, and Cosmetic Act and is explained in a symbols glossary that contemporaneously accompanies the reagent or equipment.

* * * * *

(e)(1) The labeling for analyte specific reagents (e.g., monoclonal antibodies, deoxyribonucleic acid (DNA) probes, viral antigens, ligands) shall bear the following information, except where such information is provided in the form of a symbol, provided that such symbol is either accompanied by explanatory text adjacent to the symbol or is contained in a standard that FDA recognizes under its authority under section 514(c) of the Federal Food,

Drug, and Cosmetic Act and is explained in a symbols glossary that contemporaneously accompanies the reagent:

* * * * *

(f) The labeling for over-the-counter (OTC) test sample collection systems for drugs of abuse testing shall bear the following information in language appropriate for the intended users, except where such information is provided on labels in the form of a symbol, provided that such symbol is either accompanied by explanatory text adjacent to the symbol or is contained in a standard that FDA recognizes under its authority under section 514(c) of the Federal Food, Drug, and Cosmetic Act and is explained in a symbols glossary that contemporaneously accompanies the test sample collection system:

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Dated: April 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.